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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,763	02/14/2001	Norbert Windhab	260/095	2275

34263 7590 05/01/2003

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IRVINE, CA 92618

EXAMINER

FRIEND, TOMAS H F

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/01/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/783,763

Applicant(s)

WINDHAB ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-112 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action

Status of the Application

A declaration was received on 11 June 2001 (Paper No. 3), an information disclosure statement was received on 02 November 2001 (Paper No. 4), and a supplemental information disclosure statement was received on 10 December 2001 (Paper No. 5).

Status of the Claims

Claims 1-112 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-42, drawn to a method of detecting the presence of one or more analytes, classified in class 436, subclass 538.
 - II. Claims 43-92, drawn to a method of detecting the presence of one or more analytes, classified in class 436, subclass 524.
 - III. Claims 93-95, drawn to a method for performing multiple immunological reactions on an active electronic matrix array device, classified in class 436, subclass 524.
 - IV. Claims 96-112, drawn to a kit for use in detecting a set of one or more analytes in a sample, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because:

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2. Invention IV and Inventions I-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit of Invention IV can be used in all three of the methods of Inventions I -III.

3. Inventions I-III are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example the method of Invention III is not a method of detecting the presence of one or more analytes and does require a method step including electronic biasing as found in method step b) of Invention II and method step c) of Invention I. The method of invention I requires the formation of immune complexes in solution, which is not required in the method of Invention II.

4. Because these inventions are distinct for the reasons given above and
- a. have acquired a separate status in the art as shown by their different classification ;
 - b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
 - c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Election/Restriction

5. Initially, it is noted that the present claims are drawn to methods and compositions involving “*binding immunoreactive component-pairing component member complexes*” which lack any core structure or searchable function other than binding to an analyte. Consequently, the claims are unsearchable (i.e. searching the claims would be unreasonably burdensome).

The “*pairing components*” are disclosed include p-RNA, CNA, DNA, or RNA, for example. “*Binding immunoreaction components*” are disclosed as being attached to “*pairing components*” and “*complementary pairing components*” are disclosed as being attached to test

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sites through covalent interactions, non-covalent interactions, or a specific binding such as between biotin and streptavidin, for example. Claims 1, 43, 93, and 96 are generic to a plurality of patentably distinct inventions because they encompass compositions and the use of compositions that have different chemical, physical, and immunological properties and require different conditions and/or reagents for their use and making. Therefore, different issues of enablement and patentability apply to each invention and each invention represents patentably distinct subject matter.

Claims 1, 43, 93, and 96 each link disclosed and patentably distinct inventions. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 43, 93, and 96.

In addition to electing one of Inventions I-IV above, applicants are further required to elect a single disclosed embodiment of the elected invention which specifically identifies each of the following:

A: the set of “*binding immunoreactive component-pairing component member complexes*” (e.g. structural description including all components involved and how they are structurally and functionally related to one another),

B: the pairing components (e.g. from claims 6-9) and how they relate structurally and functionally to “*binding immunoreactive component-pairing component member complexes*”,

C: the means of attachment between “*binding immunoreaction components*” and “*pairing component*”, AND

D: the means of attachment between “*complementary pairing component member*” and test site, AND

E (not required for Invention IV): specifically what method steps are included and excluded from among the possible inclusions and exclusions cited in the claims.

6. Applicants are required to provide a list of the claims that read upon the elected invention. The linking claim will be examined to the extent that it reads upon the elected invention. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the

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limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

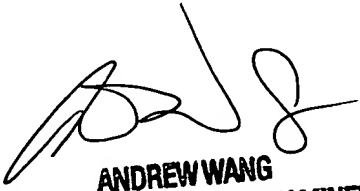
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number **(703) 308-4548**. The examiner's schedule is an increased flex-time schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
26 April 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600